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November 30, 1999

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: DOCKET NO. 97N-484S

Gentlemen:

There is a widespread understanding in the medical community that the current FDA proposal to regulate allograft bone tissue was originated more or less as an article of gamesmanship between competing medical device manufacturers. In fact, if legislated, FDA regulation of bone tissue as if it were an implanted medical device would virtually guarantee degraded medical care; it would fall into complete disuse, requiring patient autograft procedures. Sometimes autograft procedures are resorted to naturally, but this should be a medical decision not a bureaucratic one. I urge you to forego FDA regulation of allograft material as a medical device, but rather continue regulating the safety of conventional bone bank tissue.


Sincerely yours,

Bruce L. Ehni, M.D.

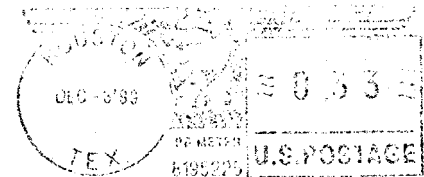
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